



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,044	02/26/1997	MARGARET BYWATER	1614-178P	1463
2292	7590	11/14/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



### DETAILED ACTION

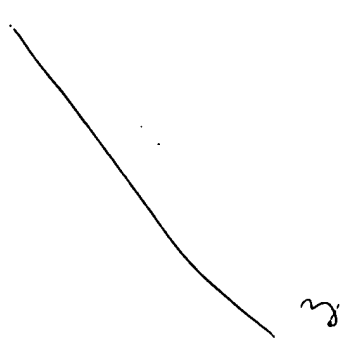
Claims 1-7, 9, 10, and 16-20 are pending and under consideration. This Office action contains new grounds of rejection. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103, Withdrawn***

The rejection of claims 1-7, 9, and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989) is withdrawn because applicant argument is persuasive.

The rejection of claims 1, 3, and 10 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989), further in view of Hedrum et al., of record, Biotechniques. 1994 Jul;17(1):118-9, 122-4, 126-9 is withdrawn because applicant argument is persuasive.

The rejection of Claims 1, 2, and 19 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989), further in view of Hollstein et al., of record (1991, Science, vol. 253, pages 49-53) is withdrawn.



***The Following Is New Ground of Rejection***

***Claim Rejections - 35 USC § 112***

Claims 1-7, 9, 10, and 16-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims says that the claimed invention is a method of prognostication of the development of neoplasia and providing guidance on treatment. It is not clear what is meant by "prognostication of the development of neoplasm" in the preamble. The sample for p53 nucleic acid analysis in the active steps of the claims is from a human neoplastic tissue or body fluid. Thus, one in the art already has the information that the subject has developed neoplasia before doing the analysis in the active steps of the claims. It is not clear how the purpose stated in the preamble of the claims is related to the active steps of the claims.

Claims 1-7, 9, 10, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for p53 mutational analysis and node status analysis, does not reasonably provide enablement for providing guidance for the treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered for enablement analysis have been stated during the prosecution history, namely the Office action mailed on 6/10/98 (note pages 5-7).

At least one part of the claimed invention in claims 1-7, 9, 10, and 16-20 is drawn to method of providing treatment guidance after the p53 mutation and nodal status determinations.

Anderssso et al., Ann Oncol. 2005 May;16(5):743-8 at Table 1, page 744 teach that one of skill in the art is able to determine p53 mutations, and also able to determine lymph node metastases, and how to use three different adjuvant therapies of CMF, TAM, CMF-TAM for breast cancer patients. Applicant argued that the claimed invention covers four different subgroups of the patients in the reply filed on 11/10/98, in response to the enablement rejection made at pages 5-7 of the Office action mailed on 6/10/98.

The specification does not teach what kinds of treatment is good for each of those patients in the different subgroups classified based on nodal status and the p53 mutational status. However, Falette et al., Cancer Res. 1998 Apr 1;58(7):1451-5, which was published almost 3 years after the effective filing date of the instant application teach at the last two sentences of the abstract "Our results suggest that P53 gene mutations could be an important factor to identify node-negative patients who have a poor prognosis in the absence of adjuvant therapy. Prospective studies should be designed to determine which therapy should be performed in this subgroup of patients." This suggests that one of skill in cancer treatment art does not know what kind of treatment is appropriate for those node negative, but p53 mutation positive breast cancer patients, let alone many other different types of cancer, even three years after the filing date of the instant application.

Art Unit: 1642

Considering the state of art, limited guidance for what kind of treatment is appropriate for each subgroups of patient, and broad scope of the claims including any cancer, undue experimentation is required to practice the full scope of the invention.

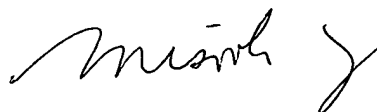
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642

A handwritten signature in cursive script, appearing to read 'Misook Yu', is written below the printed name and title.